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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,758	10/06/2006	Zuqin Lai	GLM01	3810

23900 7590 09/27/2007

J C PATENTS, INC.
4 VENTURE, SUITE 250
IRVINE, CA 92618

EXAMINER	
MI, QIUWEN	
ART UNIT	**PAPER NUMBER**
1655	
MAIL DATE	**DELIVERY MODE**
09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,758	LAI ET AL.	
	Examiner	Art Unit	
	Qiuwen Mi	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-3, in the reply filed on 8/16/2007 is acknowledged.

Claim 4 is withdrawn from further consideration as being drawn to nonelected inventions.

Claims Pending

Claims 1-4 are pending. Claim 4 is withdrawn as they are directed toward a non-elected invention group. Claims 1-3 are examined on the merits.

Claim Rejection 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increasing CD4 counts, does not reasonably provide enablement for treating AIDS. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It is well known in the art that although our understanding of pathogenesis and transmission dynamics of AIDS has become more nuanced, a cure or protective vaccine remains elusive (Simon et al, www.thelancet.com, seminar 368: 489-504, 2006). Emergence of drug resistance is the most common reason fro treatment failure. Insufficient compliance, drug side-effects, or drug-drug interactions can lead to suboptimum drug concentrations, resulting in viral rebound. Viral resistance has bee described to every antiretroviral drug and therefore poses a serious clinical as well as public-health problem. HIV-1 subtypes differ, in the sequence of multations leading to drug resistance, and some naturally occurring polymorphisms might actually modulate resistance (page 496). Mirken (AIDS Treat News. 2000 Apr 21;(341): 4-6) cited in the discussion that "AIDS medicine has made a serious mistake by relying on laboratory markers such as CD4 cell counts, and viral load...These markers are criticized as unreliable at best and devious effort to hide the failure of HIV/AIDS science at worst...", and "all HIV and viral load tests as well as T-cell counts need to be banned immediately because they are useless indicators of a person's health". The arguments against use of CD4 center around two broad issues. One is the natural variability in CD4 counts, which can be lower than average for reasons not related to AIDS. The other is whether or not CD4 numbers actually correlate with clinical prognosis. A number of studies found in the biomedical literature show that low T-cell counts do not correlate with compromised immunity, and that normal ranges from T cells in HIV negative

persons can very from 300 to 2,000...and there was absolutely no correlation between CD4 T-cell counts and clinical health" (page 4).

The invention only provides the description of a medicine preparation for increasing CD4 counts in AIDS patient up to 30%, and no description regarding whether CD4 counts are normal at the end of the treatment or it will stay 30% increased after the 6 month treatment duration. It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to treating AIDS, that Applicant is not enabled for treating AIDS as instantly claimed. Considering this evidence, the skilled artisan would necessarily need to perform tedious trial and error protocols without expectation of success in order to treat AIDS.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; *however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological

activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are confusing as they recite "Chinese medicine preparation", it is not clear whether the herbal materials are only available in China or the medicine preparation could be only used by Chinese people.

The claims 1-3 recite numbers such as "120-150", and "120-200", but it is not clear if these are percentages or particular gram/microgram amounts, and if they are present by weight of the entire composition.

Conclusion

No claim is allowed.

Claims 1-3 are free of art, as the 10-20 components could not be found being used in the art for the same purpose individually. The closest prior art is CN 1215601A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/
Patricia Leith
Primary Examiner
AU 1655